

PSJ3

Exhibit 477

From: Ducca, Anita <aducca@hda.org>
Sent: Tuesday, January 21, 2014 3:47 PM
To: Kelly, Patrick
Subject: RE: January 22 HDMA Monthly Officers Conference Call

Got it. Thanks.

From: Kelly, Patrick
Sent: Tuesday, January 21, 2014 10:42 AM
To: Bittman, Ann; Johnson, Anne
Cc: Ducca, Anita; Gallenagh, Elizabeth
Subject: FW: January 22 HDMA Monthly Officers Conference Call

For Officers Call –

Pedigree

DQSA implementation: Continues to progress rapidly. HDMA is working with an internal Implementation Task Force to develop positions on key technical issues that can be shared with the FDA.

- The immediate focus of the task force is on developing recommendations for the treatment of “suspect” product. In accordance with the law, FDA must issue its first guidance by May 26 regarding the identification and treatment of suspect products.
- The task force is also working on the standards for interoperable exchange of Transaction Information (TI), Transaction History (TH) and Transaction Statements (TS) which FDA must finalize by Nov. 27. The first step is to identify the process flows so that we can determine what needs to be passed when and where.
- And, the task force is also working to develop recommendations for the creation of the wholesaler database where distributors report to FDA on their state licensed facilities starting 1/1/15. We’re looking at appropriate formats to submit this to FDA, but the clear consensus so far is in a very simple format, e.g. possibly an excel spread sheet

PDSA: HDMA will also continue to work with the Pharmaceutical Distribution Security Alliance (PDSA) on developing consensus (insofar as consensus can be reached) positions on the above-reference items. Essentially HDMA will pursue parallel paths with the PDSA, with HDMA focusing on developing industry-specific recommendations, and do what we can to help PDSA with developing consensus recommendations as well. The former will take precedence over the latter.

Working with the States: HDMA has communicated to all 50 states regarding licensure and pedigree preemption and offered the Association as a resource, as well as begun an open dialogue with some key states. This will include a meeting with Florida’s Department of Business and Professional Regulation (DBPR) on Jan. 27th.

FDA Briefing: FDA has requested that HDMA provide their staff working on the DQSA, who are unfamiliar with distribution, with a presentation on the basics of wholesale distribution – essentially a Distribution 101. We’ve just sent them some dates to consider.

Other FDA Related issues

Citizen Petition on Hydrocodone Combination Products: The law firm Morgan Lewis has filed a Citizen Petition on behalf of an unnamed client opposing upscheduling of certain hydrocodone combination products from Schedule III to Schedule II. The petition asks FDA not to upschedule the lower dose version of these products so that “...*Hydrocodone combination products... in a strength that is lower than 5 mg*” would remain in Schedule III. There’s no final decision and FDA will likely take a little time to respond.

Controlled Substances/DEA

Drug Diversion/DEA Strategy Task Force: HDMA’s DEA/Controlled substances Strategy meeting Dec. 11 – one of the things those at the meeting requested we do was to “survey” our members about how they comply with DEA using questions similar to what we sent to DEA. [Redacted]

[Redacted]
[Redacted]
[Redacted] We’ll be sure to have this assessed and ready for discussion at the ExComm meeting so that can be factored into whether/how to release the survey responses.

Dedicated Lobbyist: HDMA has interviewed a small lobbying firm with expertise and relationships with the House Judiciary Committee. This firm has very a very good working relationship with Congressman Tom Marino (R-PA) who is the lead sponsor of legislation to put in place provisions to implement a more defined regulatory relationship between DEA and the entities it regulates. This firm is already on retainer to CAH and has offered to bring HDMA on at a very reduced rate.

NABP stakeholder group update: (Brief Ted on NABP stakeholder group and NCPO cornering of Carmen) We understand from the distributor member who attended the NABP workgroup that “next to nothing” about wholesalers has been discussed, so far.

CMS reviewing abuse prescribing practices: CMS is proposing to establish a mechanism for reviewing prescribers for abusive prescribing practices, particularly for controlled substances. We’re looking at it to determine if it may provide an opportunity to help ease DEA pressure on our members for SO monitoring. Alternatively, it may be good from a PR perspective to take to the Hill or elsewhere to explain that if DEA were to let up a little, there are other agencies now more attuned to this problem and whose efforts are more likely to be productive in preventing abusive practices.

DEA Speaker at DMC: We have invited, but have not yet had a response from DEA as to whether or not they will send a representative to speak at the DMC meeting in Palm Desert. They had previously committed to participating, but we haven’t heard any specifics.

Drug Disposal

Meeting with EPA: HDMA staff met with EPA staff on their plans for a proposed new rule on pharmaceutical product disposal. Not good news. They’re considering defining all unsellable returns, even those sent to returns processors for credit, as “waste”. If they do, our members may face considerable new federal and/or state environmental regulations for permitting, reporting, separating product returns deemed by EPA as “hazardous” from non-hazardous when returning them, and more, depending on how they write the rule. They’ll propose the rule alter this year.

GPPC Meeting

February 5-6 – Washington Marriott Hotel. Event will kick off with a Hill Day and members working (primarily the house side) to support introduction of Marino/Blackburn and talk about need for collaboration on drug abuse and diversion prevention. We have Stu Rothenberg for Dinner speaker and Congressman Marino (Tentative) for breakfast speaker. In the process of developing a Supply

Chain Panel discussion of 2014 legislative priorities. Attempting to secure participation from NCPA, NACDS, PhRMA, and GPhA government affairs representatives.

From: Bittman, Ann
Sent: Friday, January 17, 2014 10:40 AM
To: Senior Management Team
Subject: January 22 HDMA Monthly Officers Conference Call

All,

John Gray has his next monthly officers conference call on Wednesday, January 22 with Dave Neu and Ted Scherr.

Please send him any industry and association updates that should be included **by noon on Tuesday, January 21st**.

Thanks,
Ann